

Misbranding, Section 502 (a), the label statement "sterile" was false and misleading as applied to an article that was not sterile but was contaminated with viable micro-organisms. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 19, 1949. Default decree of condemnation and destruction.

2720. Adulteration and misbranding of estrogenic substance. U. S. v. 48 Vials
* * *. (F. D. C. No. 26613. Sample Nos. 11258-K, 11271-K.)

LABEL FILED: February 24, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about November 24, 1948, by Estro Chemical Co., Inc., from New York, N. Y.

PRODUCT: 48 10-cc. vials of *estrogenic substance* at Union City, N. J. The product was shipped under a label identical to that set forth below, except that the brand name "Aqua-Gyne" and the name and address of the manufacturer, the Estro Chemical Co., appeared thereon in place of the brand name "Aquacrine" and the name and address of the distributor, the Endocrine Co.

LABEL, IN PART: "Aquacrine Aqueous Estrogenic Substance * * * Distributed By Endocrine Company, Union City, N. J."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 97 percent of the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc * * * contains * * * Estrogenic Substances (predominantly Estrone) * * * (Ketosteroids as Estrone, approximately 97% by potency). * * * equivalent to 20,000 I. U. (assayed in terms of Estrone)" was false and misleading as applied to the article, which contained materially less than 97 percent of the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

DISPOSITION: May 2, 1949. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for experimental purposes.

2721. Adulteration and misbranding of chloro-iodo-hydroxy-quinoline. U. S. v. 1 Drum * * *. (F. D. C. No. 26938. Sample No. 11345-K.)

LABEL FILED: March 21, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about May 25, 1948, by the R. S. A. Corp., from Ardsley, N. Y.

PRODUCT: 1 25-pound drum of *chloro-iodo-hydroxy-quinoline* at South Hackensack, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), di-iodo-hydroxy-quinoline had been substituted in part for chloro-iodo-hydroxy-quinoline.

Misbranding, Section 502 (a), the name "Chloro-Iodo-Hydroxyquinoline" was false and misleading as applied to the article, which consisted of a mixture of chloro-iodo-hydroxy-quinoline and di-iodo-hydroxy-quinoline.

DISPOSITION: May 2, 1949. Default decree of condemnation. One pound of the product was ordered delivered to the Food and Drug Administration, for experimental purposes, and the remainder was ordered destroyed.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE
AND MISLEADING CLAIMS****DRUGS FOR HUMAN USE***

2722. Misbranding of Lemel. U. S. v. 300 Dozen Packages * * *. (F. D. C. No. 26006. Sample No. 2748-K.)

LIBEL FILED: November 4, 1948, District of Columbia.

ALLEGED SHIPMENT: On or about October 28, 1948, by the Serutan Co., from Newark, N. J.

PRODUCT: 300 dozen packages of *Lemel* at Washington, D. C.

LABEL, IN PART: (Package) "*Lemel* 20 Packets Each Packet Contains Vitamin C Equal to 7 Lemons (Av.) Ingredients: Dextrose, lemon powder, oil of lemon, oil of lime, potassium bitartrate and tartaric acid (from grapes), potassium citrate, ascorbic acid, thiamin hydrochloride, riboflavin, niacin, niacinamide, potassium phosphate, magnesium carbonate, calcium carbonate. Lo-Calory Food Corp., New York, N. Y. Each *Lemel* Packet Contains: Vitamin C . . . 150 mgs. (5 MDR), Vitamin B₁ . . . 5 mgs. (5 MDR), Riboflavin . . . 2 mgs. (1 MDR), Niacin . . . 25 mgs.*, Niacinamide . . . 25 mgs.* MDR-Minimum Daily Requirement. *MDR not established."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in a leaflet enclosed in each package of the product were false and misleading: "Lemonade has long been used in colds, grippe and flu. Many who suffer from joint aches and pains are accustomed to taking the juice of 1 or more lemons as a morning drink. Today, in *Lemel* you can get the Vitamin C value of the juice of 7 Average Lemons * * * Use *Lemel* regularly and faithfully." The statements represented and suggested that the article was effective in the treatment of colds, grippe, flu, and joint aches and pains. The article was not effective in the treatment of such diseases, symptoms, and conditions.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 14293.

DISPOSITION: December 15, 1948. Lo-Calory Food Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

2723. Misbranding of lemon juice. U. S. v. 22 Cases * * * (and 1 other seizure action). (F. D. C. Nos. 26092, 26093. Sample Nos. 18293-K, 18294-K.)

LIBELS FILED: November 24, 1948, Northern District of Ohio.

ALLEGED SHIPMENT: On or about September 1, 1948, by the Puritan Company of America, from Chicago, Ill.

PRODUCT: 77 cases, each containing 24 1-pint bottles, of *lemon juice* at Cleveland, Ohio.

LABEL, IN PART: "Realemon Brand 100% Real California Lemon Juice."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "For Health and Regularity * * * For Fighting or Breaking Colds" were false and misleading since use of the product would not promote health and regularity, and the product would not be effective in the treatment of colds.

*See also Nos. 2715-2717, 2719-2721.